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08/967243

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/967,243	11/05/97	LASKY	L P0833P1C1

HM11/0901

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EXAMINER
GAMBEL P
ART UNIT PAPER NUMBER
1644 23

DATE MAILED: 09/01/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 11/5/97; 6/4/98
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1, 15-25, 28 is/are pending in the application.
Of the above, claim(s) 15-25 is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1, 28 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number)
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 21
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. Applicant's Status Inquiry, filed 6/9/98 (Paper No. 22) is acknowledged.
This Office Action should serve in response to said inquiry.

3. Applicant's amendments, filed 11/5/97 (Paper Nos. 19/20), are acknowledged.
Claims 8-12 and 26 have been canceled. Claims 2-7, 13, 14 and 27 have been canceled previously.
Claim 1 has been amended.
Claim 28 has been added.

Claims 15-25, drawn to nonelected inventions have been withdrawn from consideration.

Claims 1 and 28 are under consideration and being acted upon.

4. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's arguments, filed 11/5/97 (Paper No. 12).
The rejections of record can be found in previous Office Actions (Paper Nos. 7/13/16).

5. Applicant should update the status of the parent applications on the first line of the specification. USSN 08/256, 418 is now abandoned.

6. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84.
Please see the form PTO-948 previously sent in Paper No. 7.

As pointed out previously, it was noted that applicant has amended the Brief Description of the Drawings to include Figure 2, however there is no Figure 2.

Applicant will submit formal drawings upon the indication of allowable subject matter.

7. Upon reconsideration of applicant's amended claims, filed 11/5/97 (Paper No. 20); the previous rejection under 35 U.S.C. § 112, first paragraph, as it would apply to the instant claims has been withdrawn.

8. Claims 1 and 28 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: "inhibiting the binding of native L-selectin to peripheral lymphoid tissue" and "contacting said L-selectin".

The claims now recite inhibiting the binding of "L-selectin" rather than "L-selectin expressing cells" or "L-selectin interactions". Therefore, the claims read on inhibiting soluble L-selectin to peripheral lymphoid tissue rather than inhibiting L-selectin expressing cells from interacting with peripheral lymphoid tissue, as disclosed in the application as filed. Further, the recitation of "native L-selectin" is not readily apparent from the specification as filed. The specification as filed does not provide a written description or set forth the metes and bounds of these phrases. The specification does not provide landmarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope and nature of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

9. Claims 1 and 28 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite in the recitation of "inhibiting the binding of native L-selectin to peripheral lymphoid tissue" and "contacting said L-selectin" because the disclosed and intended claimed methods are drawn to inhibiting the interaction of L-selectin and peripheral lymphoid tissue and to inhibiting L-selectin expressing cells in contrast to the current recitation of inhibiting L-selectin itself. Therefore, the claimed methods are confusing and ambiguous as to the intent of the claimed methods.

There is insufficient direction or guidance provided to assist one skilled in the art in therapeutic methods of "inhibiting the binding of native L-selectin to peripheral lymphoid tissue" in patients of need, wherein the L-selectin or soluble L-selectin is a target of such therapy. Again, the disclosed and intended therapeutic methods are drawn to inhibiting L-selectin mediated interactions and to inhibiting L-selectin expressing cells in patients of need. There is insufficient guidance and direction in the application as filed to treat patients in need, wherein the therapeutic modality is to inhibit L-selectin itself from binding to peripheral lymphoid tissue. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. It appears that undue experimentation would be required of one skilled in the art to practice the claimed methods using the teaching of the specification alone.

The applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter.

10. Claim 28 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation of "CD34 isolated from peripheral lymph nodes" recited in claim 28 is essentially the same as that recited in claim 1 and does not further limit claim 1.

11. Claims 1 and 28 are rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Butcher et al. (U.S. Patent No. 5,538,724; see entire document) essentially for the reasons of record set forth in the previous Office Actions (Paper No. 7/13/16).

Applicant's arguments, filed 11/5/97 (Paper No. 20), have been fully considered but are not found convincing.

Applicant argues that applicant cannot find the alleged teaching either at column 5, paragraph 2 or at other parts of the patent. In contrast to applicant's assertions that this reference only teaches or only concerns the use of antibodies. However, this section discloses that: "soluble forms of the addressin may serve to bind to the homing receptor and inhibit binding of the homing receptor to the addressin, where the soluble form may be a protein or fragment thereof These proteins may include sequences having the same or substantially the same sequence as the addressin". Again, Butcher et al. teaches the use of modulating leukocyte extravasation associated with inflammatory diseases encompassed by the claimed inventions (e.g. columns 3-6, Table 1) with soluble forms of the addressin identified by MECA-79 (e.g. column 5, paragraph 2) and various formulations and combinations of said antagonists (columns 3-6). Columns 17-22 disclose the PNad or MECA-79 antigen and its role as a vascular addressin for LECAM-1. Again, although the reference is silent about the CD34 specificity, the PNad or MECA-79 antigen or addressin disclosed in Butcher et al. is the same as the claimed CD34 specificity. Also the LECAM-1 specificity disclosed by Butcher et al. is the same as the claimed L-selectin specificity. Therefore the claimed and referenced methods to inhibit L-selectin binding to peripheral lymphocyte tissues in various therapeutic modalities appear to be the same.

It is the burden of the applicant to show the unobvious difference between the claimed and disclosed methods and compositions. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

Therefore applicant's arguments are not found persuasive.

12. Claims 1 and 28 are rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Lasky et al. (U.S. Patent No. 5,304,640) essentially for the reasons of record set forth in the previous Office Actions (Paper Nos. 7/13/16).

Applicant's arguments, filed 11/5/97 (Paper No. 20), in conjunction with the Lasky/Rosen/Singer declaration under 37 C.F.R. § 1.132, filed 9/15/97 (Paper No. 15), have been fully considered but are not found convincing.

The Lasky/Rosen/Singer declaration under 37 C.F.R. § 1.132 is deficient because there is no declaration from the non-instant-inventor Imai disclaiming his contribution to the disclosed but not claimed teachings of Lasky et al. See MPEP 715.01(a) and In re Facius, 408 F.2d 1396, 161 USPQ 294 (CCPA 1969).

Alternatively, Lasky et al. minus Imai (i.e. Lasky, Rosen and Singer) would still be prior art as being done by another in view that the instant application is by Lasky, Baumheuter, Rosen and Singer. Also, the Lasky/Rosen/Singer declaration under 37 C.F.R. § 1.132 states that "the invention using Sgp90 for the treatment of symptoms or conditions associated with the excessive binding of circulating leukocytes to endothelial cells, as disclosed but not claimed in the '640 patent, was conceived solely by us". Therefore, it does not appear that Baumheuter is an inventor of the claimed invention.

Applicant's arguments relying upon the Lasky/Rosen/Singer declaration under 37 C.F.R. § 1.132 alone are not found persuasive.

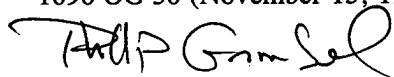
13. Claims 1 and 28 are rejected under 35 U.S.C. § 103 as being unpatentable over Butcher et al. (U.S. Patent No. 5,538,724) or Lasky et al. (U.S. Patent No. 5,304,640) in view of Lasky et al. (CSHSQB, 1992; 1449, #35), Berg et al. (J. Cell Biol., 1991; 1449, 1449, #8) or Imai et al. (J. Cell Biol. 1991; 1449, #28), Sutherland et al. (Leukemia, 1988; 1449, #51), Lasky et al. (U.S. Patent No. 5,098,833; 1449, #2), Watson et al. (Nature, 1991; 1449, #55), Fina et al. (Blood, 1990; 1449, #22) and Schlingemann et al. (Lab. Invest., 1990; 1449, #42) essentially for the reasons of record set forth in the previous Office Actions (Paper Nos. 7/13/16).

Applicant's arguments, filed 11/5/97 (Paper No. 12), in conjunction with the Lasky/Rosen/Singer declaration under 37 C.F.R. § 1.132, filed 9/15/97 (Paper No. 15), have been fully considered but are not found convincing. Applicant's arguments and the examiner's rebuttal concerning Butcher et al. (U.S. Patent No. 5,538,724) or Lasky et al. (U.S. Patent No. 5,304,640) have been addressed above in sections 11 and 12. Applicant's arguments are not found persuasive.


14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



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